

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSENDER FOR PATENTS PO Box 1430 Alexandria, Virginia 22313-1450 www.wopto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/705,615	11/10/2003	Xiaobo Wang	ACE-00101.P.1.2-US	4696	
24322 75500 0320020000 DAVID R PROTON & ASSOCIATES APC 5850 OBERLIN DRIVE SUITE 300 SAN DIEGO, CA 92121			EXAM	EXAMINER	
			BEISNER, WILLIAM H		
			ART UNIT	PAPER NUMBER	
			1797		
			MAIL DATE	DELIVERY MODE	
			03/20/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/705.615 WANG ET AL. Office Action Summary Examiner Art Unit WILLIAM H. BEISNER 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 17 December 2007. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4)\(\times\) Claim(s) 1.6.8-11.24.25.28.29.43.50.51.62.65.68.69 and 139-156 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1.6.8-10.24.25,28.29,43,50,62,65,68,69 and 139-141 is/are rejected. 7) Claim(s) 11,51 and 142-156 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date \_\_\_ Notice of Draftsperson's Patent Drawing Review (PTO-948). 5) Notice of Informal Patent Application

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 12/17/2007.

6) Other:

Art Unit: 1797

### DETAILED ACTION

#### Continued Examination Under 37 CFR 1.114

 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/2007 has been entered.

# Information Disclosure Statement

The information disclosure statement filed 12/17/2007 has been considered and made of record.

### Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1, 6, 9, 10, 24, 43, 50, 62, 65, 68, 69 and 139 are rejected under 35 U.S.C. 102(e) as being anticipated by Sparks (US 6,637,257).

Art Unit: 1797

With respect to claim 1, the reference of Sparks discloses a device (See Figures 3 and 4) that is structurally capable of monitoring cell migration or invasion of a biological particle including an upper chamber (30); a lower chamber (30) comprising at least two electrodes (20,22); and a biocompatible porous membrane (12) having a porosity (14) sufficient to allow cells to migrate therethrough, wherein the membrane is disposed in the device so as to separate the upper and lower chambers from one another, wherein the at least two electrodes are disposed on the membrane; wherein cell can contact one or more of the electrodes; wherein the electrodes have substantially the same surface area (See Figure 2) and further wherein contact of a cell with the electrodes provides a detectable change in impedance between or among the electrodes (See column 4, lines 14-31). Note, while the upper chamber in Figures 3 and 4 includes the electrodes, the device is structurally the same as that instantly claimed regardless of the orientation of the device. Statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 6, the electrodes (20,22) are connected to impedance analyzer (42).

With respect to claim 9, the membrane (12) can include a coating for promoting the attachment of cells thereto (See column 4, lines 31-36).

With respect to claim 10, the device includes electrical traces and a connection means (See Figures 2 and 5).

With respect to claim 24, in the absence of further positively recited structure, the membrane is considered to be a flexible biocompatible membrane.

With respect to claim 43, the membrane (12) divides the device into upper and lower chambers

Art Unit: 1797

With respect to claim 50, the device includes at least four electrodes and includes an array of electrode pairs (See Figure 2).

With respect to claim 62, the membrane can have a pore size between 1 and 30 microns (See column 14, lines 1-13).

With respect to claim 65, the membrane (12) can include a coating for promoting the attachment of cells thereto (See column 4, lines 31-36).

With respect to claims 68 and 69, the device is structurally capable of holding compounds as recited in these claims. Note these compounds are considered to be material worked on and not structural elements of the claimed device (See MPEP 2115).

With respect to claim 139, the electrodes are interdigitated and have the same surface area (See Figure 2).

### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
  obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1797

4. Considering objective evidence present in the application indicating obviousness or nonohyiousness

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

 Claims 140 and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (US 6,637,257).

The reference of Sparks has been discussed above.

With respect to the shape and dimensions of claims 140 and 141, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the design of the interdigitized electrodes based merely on the types of cells to be detected in the system while maintaining the efficiency of the detection system.

Claims 8, 24, 25, 28, 29, 43, 50, 62, 65, 68, 69 and 139 are rejected under 35 U.S.C.
 103(a) as being unpatentable over Sparks (US 6,637,257) in view of Shah (US 5,247,827).

The reference of Sparks has been discussed above.

With respect to claim 24, if the membrane of the reference of Sparks is not considered to be "flexible", the reference of Shah discloses that it is known in the art to provide interdigitated Application/Control Number: 10/705,615

Art Unit: 1797

electrodes on membranes that are made of polymers and would be flexible (See column 2, lines 33-50).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ alternative membrane materials within the device of the primary reference as evidenced by the reference of Shah while maintaining the required particle filtration and interdigitated electrodes for detection of the filtered particles.

With respect to claims 8 and 25, the resulting membrane would be made of a polymer material. With respect to the thickness of the membrane, one of ordinary skill in the art would be capable of determining the optimum thickness of the membrane based on the size of the device and/or materials to be filtered while maintaining the structural integrity of the membrane.

With respect to claim 28, the membrane (12) can include a coating for promoting the attachment of cells thereto (See column 4, lines 31-36).

With respect to claim 29, while the reference of Sparks discloses the use of cell attraction coatings, the reference is silent with respect to the specific coating used.

The use of extracellular matrix material is well known in the art for attracting cells to a surface for adhesion. As a result, it would have been obvious to one of ordinary skill in the art to provide the membrane of the primary reference with extracellular matrix for the known and expected result of adhering or attracting cells as is required of the primary reference.

With respect to claim 43, the membrane (12) divides the device into upper and lower chambers.

With respect to claim 50, the device includes at least four electrodes and includes an array of electrode pairs (See Figure 2).

Art Unit: 1797

With respect to claim 62, the membrane can have a pore size between 1 and 30 microns (See column 14, lines 1-13).

With respect to claim 65, the membrane (12) can include a coating for promoting the attachment of cells thereto (See column 4, lines 31-36).

With respect to claims 68 and 69, the device is structurally capable of holding compounds as recited in these claims. Note these compounds are considered to be material worked on and not structural elements of the claimed device (See MPEP 2115).

With respect to claim 139, the electrodes are interdigitated and have the same surface area (See Figure 2).

# Allowable Subject Matter

- 10. Claims 11, 51 and 142-156, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 11. The following is a statement of reasons for the indication of allowable subject matter:

Claim 11 would be allowable because the prior art of record fails to teach or fairly suggest introducing cells on the downstream side of the membrane relative to the electrode pairs in the device of Sparks for monitoring the migration or invasion of cells through the membrane. The reference of Sparks requires that cells are introduced on the upstream side of the membrane relative to the electrode pairs which is on the opposite side of the membrane when compared to instant claim 11.

Claims 51, 142 would be allowable because the prior art of record fails to teach or fairly suggest combining the membrane device of the reference of Sparks with a structure that defines a plurality of isolated fluid containers wherein at least one of the containers comprise a single IDES or CCES.

Page 8

Claims 143-156 would be allowable because the prior art of record fails to teach or fairly suggest combining the membrane device of the reference of Sparks with a plate the comprises one or more wells wherein the membrane device separates the well into upper and lower chambers.

## Response to Arguments

12. Applicant's arguments, see pages 17-39, filed 12/17/2007, with respect to the rejection(s) of claim(s) 1,2,6,9-11,24,25,28,29,36,43,50,51,62,65,68,69,138-145,147 and 151-153 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sparks (US 6,637,257) under 35 USC 102(e) and 35 USC 103.

#### Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues, to Fri. and alt. Mon. from 6:15am to 3:45pm.

Art Unit: 1797

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/ Primary Examiner Art Unit 1797

WHB